THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant(s):	K. Bortlik et al.
Appl. No.:	10/057,660
Conf. No.:	4348
Filed:	January 25, 2002
Title:	PRIMARY COMPOSITION COMPRISING A LIPOPHILIC BIOACTIVE COMPOUND
Art Unit:	1651
Examiner:	R.A. David
Docket No.:	112701-593

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on February 2, 2007. This Appeal is taken from the Final Rejection in the Office Action dated August 3, 2006 and the Advisory Action dated December 11, 2006.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec S.A. by virtue of an Assignment dated April 17, 2002 and recorded at reel 012823, frame 0530 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 65-76, 78-82 and 86-93 are pending in the above-identified patent application. Claims 65-76, 78-82 and 86-93 stand rejected. Therefore, Claims 65-76, 78-82 and 86-93 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Final Office Action was mailed on August 3, 2006. Appellants filed a Response on November 22, 2006 in reply to the Final Office Action. An Advisory Action was mailed on December 11, 2006. In the Advisory Action, the Examiner entered the amendments but maintained the anticipation rejections. A copy of the Final Office Action and the Advisory Action are attached as Exhibit A and Exhibit B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 65 is directed to a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 11-14) and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 21-26).

Independent Claim 90 is directed to a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 11-14) and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 21-26), wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition (page 6, lines 10-12) and the whey protein is present in an amount of about 5 to 90% by weight of the composition (page 6, lines 13-14) and wherein the whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1 (page 6, lines 14-18).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the reference numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the reference numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 65-76, 78-82 and 86-93 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,643,623 to Schmitz et al. ("*Schmitz*"). A copy of *Schmitz* is attached herewith as Exhibit C.

VII. ARGUMENT

A. LEGAL STANDARDS

Anticipation under 35 U.S.C. §102

Anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added).

Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). In this regard, a reference disclosing "substantially the same thing" is not enough to anticipate. *Jamesbury Corp. v. Litton Indust. Prod., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985). A reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found.

To establish inherent anticipation, the Federal Circuit has stated that "extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Inherency, however, may not be established by probabilities or possibilities.* The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added).

In relying on inherency, the Patent Office requires an examiner to supply an applicant with a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). If the examiner is successful in showing a sound basis, for example, that the products of the applicant and the prior art are the same, the burden then shifts to the applicant to show that they are not. See, MPEP 2112.

B. THE CLAIMED INVENTION

Independent Claim 65 recites, in part, a primary composition for oral use. The composition comprises a mixture of at least one lipophilic bioactive compound and a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound.

Independent Claim 90 recites, in part, a primary composition for oral use. The composition comprises a mixture of at least one lipophilic bioactive compound and a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. The lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition. The whey protein is present in an amount of about 5 to 90% by weight of the composition. The whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.

C. THE REJECTION OF CLAIMS 65-76, 78-82 AND 86-93 UNDER 35 U.S.C. §102(b) SHOULD BE REVERSED BECAUSE *SCHMITZ* DOES NOT ANTICIPATE THE CLAIMED INVENTION

Regarding Claims 65-76, 78-82 and 86-93, the Examiner alleges that *Schmitz* discloses every element of the present claims. Appellants respectfully submit that the anticipation rejection in view of *Schmitz* is improper and traverse the rejection for at least the reasons set forth below.

1. The *Affidavit* shows that *Schmitz* fails to disclose a mixture of at least one lipophilic bioactive compound and a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound

Independent Claims 65 and 90 recite, in part, a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound ("LBC"). As such, the composition of the present claims is directed to a homogenous mixture of LBC within whey protein in an amount effective to increase bioavailability of the LBC. For

example, rather than being in a discrete form, such as an encased core as in *Schmitz*, the LBC of the present claims is distributed uniformly through the protein component thereby providing the unexpected and important benefits of increased bioavailability of the LBC. In fact, the present claims are focused on distribution of the lipophilic compound in a matrix of whey protein and not as a core in an encapsulated product. This is due to the fact that the emulsifiers naturally present in tomato oleoresin, for example, or other added emulsifiers, replace the proteins in the interface, which precludes an encapsulation process. The Examiner has failed provide any support in *Schmitz* for this novel element.

In contrast, *Schmitz* fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound as required, in part, by independent Claims 65 and 90. In fact, *Schmitz* fails to provide any guidance or support regarding same.

Instead, *Schmitz* is directed to a health food product containing a first component in the form of a discrete portion (i.e. core) from a second component provides enhanced in vivo oxidative defense indices and prevents or attenuates exercise-induced in vivo oxidative stress as indicated by cellular and/or tissue modification. The first component includes an antioxidant mixture containing a blend of antioxidants selected from all-trans beta-carotene, a mixture of cis beta-carotenes, all-trans alpha-carotene, a mixture of cis alpha-carotenes, all-trans lycopene, a mixture of cis lycopenes, all-trans gamma-carotene, a mixture of cis gamma-carotenes, zeta-carotene, phytofluene, phytoene, vitamin C, vitamin E and curcumin. Internalization and integration of the above nutrients within a lipid containing core of the food product facilitates absorption of the fat-soluble components in the gastrointestinal tract following consumption, increases shelf-life and minimizes degradation of these labile compounds by minimizing exposure to heat, light and/or oxygen, and prevents disadvantageous yellow/orange coloration of the outer material of the food product.

The Examiner alleges that *Schmitz* teaches food product compositions comprising 20-40% whey, 0.1-1% carotenoids and 1.5-3.5% vitamin E and C in Example 6. Example 6 of *Schmitz* discloses a first component containing 10-20% of whey protein that is used as carrier in the lipid-containing core and 0.1-1% cartenoid blend. The second component contains only carrier compounds and no LBC, as specified in the description stating "[t]he second component comprises a carbohydrate and/or fat and/or protein, and other nutritive and non-nutritive

compounds." See, *Schmitz*, column 2, line 66 to column 3, line 1. Consequently, the *Schmitz* composition is in an encapsulated form and therefore heterogeneous. Appellants respectfully submit that one skilled in the art would find that *Schmitz* entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by whey protein as a matrix.

Moreover, to demonstrate the failure of the referenced art to teach the claimed elements, Appellants submitted an Affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit D) on February 2, 2007. The *Affidavit* demonstrates the deficiencies of the prior art. As supported by the *Affidavit*, *Schmitz* fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound as required, in part, by the present claims. Instead, *Schmitz* is directed to a health food product containing a first component in the form of a discrete portion within a second component. The first component includes antioxidants in a lipid containing core of the food product. As a result, because *Schmitz* teaches including antioxidants in a lipid-based core, the antioxidants in *Schmitz's* composition are in an internalized and heterogeneous form, which is distinguishable from the homogenous mixture of the LBC and whey protein in accordance with the present claims.

In the Advisory Action, the Examiner alleges that the present claims do not require that the composition be homogenous and, thus, the argument that *Schmitz* does not teach a homogenous mixture of LBC and whey is not commensurate in scope with the claims. See, Advisory Action, page 2. However, Appellants respectfully submit that one having ordinary skill in the art would understand that the claimed "mixture" of the present claims requires a homogenous dissolution as opposed to a product containing two discrete portions as in *Schmitz*.

For example, the term "mixture" is defined as "the state of being mixed." See, Merriam-Webster OnLine, definition of "mixture." Merriam-Webster OnLine further defines "mix" as "combining or blending into one mass." See, Merriam-Webster OnLine, definition of "mix." In the specification, several examples illustrate that the whey protein may be dissolved in a solvent. Similarly, the LBC may also be dissolved in another solvent. Upon dissolution of the whey protein and the LBC, the solutions are then mixed before the solvents are evaporated. See, specification, page 8, line 19-page 10, line 11. Therefore, as evidenced by the specification, one having ordinary skill in the art would understand that "mixing" the two solutions means combining the solutions or blending the solutions into one homogenous solution.

Similarly, Merriam-Webster OnLine further defines "homogenous" as being of uniform structure or composition throughout. See, Merriam-Webster OnLine, definition of "homogenous." Since the specification clearly illustrates several examples where the LBC is dissolved into one solvent, the whey protein is dissolved into another solvent, and the two solutions are mixed (i.e. combined or blended into one mass) before evaporating the solvent, one having ordinary skill in the art would understand that the resulting mixture is a homogenous blend of the LBC and whey protein. Thus, in view of the specification, one having ordinary skill in the art would understand that the LBC of the present claims is mixed into and throughout the whey protein matrix in a homogenous manner (i.e. there is no discrete separation of the LBC and the whey protein).

In contrast to the present claims, *Schmitz* discloses a health food product containing a first component in the form of a discrete portion (i.e. core) from a second component. Appellants respectfully submit that one having ordinary skill in the art would not use the term "mixture" when describing the relationship of a first the inner core and a second outer component of a product. Instead, they would be considered adjacent or discrete. A "mixture," on the other hand, refers to a greater level of integration of two components rather than placing them next to each other.

As illustrated by the Figures in *Schmitz* (Figures 1-5), the first component is clearly not mixed with the second component in the same way as required by the present claims. For example, the product is illustrated as having a discrete, core-like component and a distinct second component. One of ordinary skill in the art would recognize that one could not achieve the illustrated product structure by mixing the two separate portions. Such mixing could not provide a distinct first component, but rather would produce a more intimate/homogenous mixture of the first and second portions. Thus, it would be clear to one of ordinary skill in the art that the "mixture" of the present claims refers to producing a more intimate/homogenous mixture of LBC and whey protein than that provided by the food product in *Schmitz*.

Further, in part, the propriety of this anticipation rejection lies in the interpretation of the claim language "comprising a *mixture* of" (emphasis added). To properly interpret claim language, the Federal Circuit has held that claims must be read in view of the specification, of which they are a part. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). Moreover, intrinsic evidence in the form of the patent specification should guide claim

construction. Along these lines, the Federal Circuit recently reinforced the importance of the specification when interpreting claim language:

> The claims, of course, do not stand alone. Rather, they are part of "a fully integrated written instrument," *Markman*, 52 F.3d at 978, consisting principally of a specification that concludes with the claims. For that reason, claims "must be read in view of the specification, of which they are a part." *Id.* at 979. As we stated in *Vitronics*, the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; *it is the single best guide to the meaning of a disputed term*." 90 F.3d at 1582.

Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (emphasis added). Therefore, the specification remains the "single best guide" to interpreting the term "mixture" as used by Appellants in the specification. Moreover, as demonstrated above, the specification should be read as providing a homogenous mixture of LBC and whey protein. Thus, one having ordinary skill in the art would understand that the LBC is homogenously mixed into and throughout the whey protein matrix in view of the specification (i.e. there is no distinct separation of the LBC and whey protein). It is axiomatic that the Appellants' definition of a term controls how that term is interpreted.

2. The *Affidavit* shows that *Schmitz* fails to disclose enhancing the bioavailability of a lipophilic bioactive compound using whey protein

In addition to teaching the inclusion of an antioxidant mixture in a food product only in an encapsulated/discrete form, *Schmitz* fails to disclose or suggest enhancing bioavailability of the carotenoid blend. Rather *Schmitz* only contemplates using whey protein as a carrier. For example, *Schmitz* specifies that the antioxidants are preferably localized in a lipid-based carrier within the food product to promote absorption and digestion of the carotenoid blend and curcumin. See, *Schmitz*, column 3, lines 19-22. *Schmitz* only cites whey protein as an example of different kinds of proteins that can be used as a carrier while its important function related to bioavailability is not recognized or appreciated. Appellants respectfully submit that one skilled in the art would find that *Schmitz* entirely urges antioxidants that are localized in a lipid-based carrier within the food product and does not suggest enhancing the bioavailability of the cartenoid blend.

As supported by the *Affidavit*, *Schmitz's* product fails to achieve increasing the bioavailability of the LBC with whey protein in accordance with the present invention. *Schmitz* specifies that the antioxidants are preferably localized in a lipid-based carrier within the food product. See, *Schmitz*, column 3, lines 19-22. In contrast to *Schmitz*, the composition of the present claims is directed to a homogenous mixture of LBC within whey protein in an amount effective to increase bioavailability of the LBC. For example, rather than being in a lipid-based carrier as in *Schmitz*, the LBC of the present claims is distributed uniformly through a whey protein thereby providing the unexpected and important benefits of increased bioavailability of the LBC. Appellants respectfully submit that one skilled in the art would find that *Schmitz* entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by a whey protein matrix.

The Examiner alleges that the present claims are not patentable over *Schmitz* because *Schmitz* inherently posses the ability to increase the bioavailability of the LBC with whey protein. See, Office Action, page 5. Specifically, the Examiner asserts that "the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." *Id.* However, Appellants respectfully submit that *Schmitz* does not inherently posses the advantages of the present claims.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *See*, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Inherency, however, may not be established by probabilities or possibilities.* The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added). Moreover, at the patent prosecution stage, the Patent Office requires an examiner to supply an applicant with a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). Not only has this

standard not been met, Appellants have submitted an *Affidavit* that illustrates the opposite, as is demonstrated above.

As detailed above, inherency requires that the cited references necessarily (i.e. always or automatically) possess the claimed elements. *See, e.g., Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1381-82 (Fed. Cir. 2003). In other words, the food products disclosed by *Schmitz* would have be required to always result in an increased bioavailability of the LBC with whey protein to meet the present claims. However, Appellants have demonstrated that this is not the case because the embodiments disclosed by *Schmitz* do not possess all of the elements of the present claims. See, *Affidavit*. Specifically, Appellants have demonstrated that examples having LBC mixed throughout the whey protein matrix show an increased bioavailability of the LBC. In contrast, the embodiments of *Schmitz* do not provide homogenously mixed first and second components, as was discussed previously and, thus, do not always posses the advantages of the present claims.

Appellants submit that they are not required to test every potential embodiment to show that they do not disclose the claimed properties. Moreover, the Examiner has not demonstrated that there is any reason that any of the other embodiments would meet the requirements of the present claims. Accordingly, Appellants submit that the inherency argument is improper and that *Schmitz* does not anticipate the present claims.

In sum, the cited reference fails to provide or recognize a solution to the present technical problem of enhancing the bioavailability of the LBCs as Appellants' invention has done. *Schmitz* only teaches ways to protect compounds from oxidation via internalization or containing within a lipid core and not increase the bioavailability of the LBC by dispersion of the LBC in a matrix of whey proteins as required, in part, by the present claims. While *Schmitz* may have sought to provide bioactive compounds for health-related purposes, it does not recognize or even achieve the bioavailability-enhancing function of whey protein that can be utilized by mixing the whey protein with an LBC.

For at least the reasons discussed above, *Schmitz* does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

2. The rejections under 35 U.S.C. §102(b) should be reversed because the *Affidavit* properly overcomes the anticipation rejections of the pending claims

Appellants respectfully submit that the *Affidavit* properly overcomes the anticipation rejection of the pending claims with respect to the cited reference. In this regard, the *Affidavit* sufficiently and properly evidences that *Schmitz* fails to explicitly or inherently disclose or suggest compositions within the scope of the present invention. The *Affidavit* shows that the cited reference fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the LBC. Further, the *Affidavit* properly evidences that the cited reference fails to achieve increasing the bioavailability of the LBC with whey protein.

Moreover, Appellants provide examples regarding the novel composition comprising a mixture of at least one LBC and a whey protein in an amount effective to increase the bioavailability of the LBC. The improved composition provides, for example, the advantage that, when the LBC is mixed with a whey protein to form a mixture, the present invention makes available to a subject a LBC-containing composition with better bioavailability compared to consuming a LBC alone. The specification discloses particular examples regarding administration of the claimed composition and has shown that the composition's LBC availability is comparable to that of tomato puree or paste, which are products known to have the best bioavailability of lycopene. *See*, specification, page 10, line 18 to page 11, line 10.

For at least the reasons discussed above, *Schmitz* fails to teach, suggest, or even disclose independent Claims 65 and 90, and Claims 66-76, 78-82 and 86-93 that depend from either Claim 65 or Claim 90, and thus, fails to anticipate the present claims. Accordingly, Appellants respectfully request that the rejections of Claims 166-76, 78-82 and 86-93 be reversed.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish anticipation under 35 U.S.C. §102 with respect to the rejections of Claims 65-76, 78-82 and 86-93. Accordingly, Appellants respectfully submit that the anticipation rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge $500 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-593 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

Dated: March 28, 2007

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/057,660

65. Primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound.

66. Primary composition according to claim 65, wherein the lipophilic bioactive compound is obtained, extracted, enriched or purified from a plant, microorganism, yeast or product of animal origin.

67. Primary composition according to claim 66, wherein the plant is tomatoes, soya, green tea, green coffee beans, spices, grapes, cocoa, ginger or cereals.

68. Primary composition according to claim 66, wherein the microorganism is any type of bacterium which produces a lipophilic bioactive compound.

69. Primary composition according to claim 66, wherein the yeast is a yeast which produces a lipophilic bioactive compound.

70. Primary composition according to claim 66, wherein the product of animal origin is chosen from the group consisting of a liver extract and a milk fraction.

71. Primary composition according to claim 66, wherein the lipophilic bioactive compound is a carotenoid, polyphenol, lipophilic vitamin, flavonoid, isoflavone, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, or retinoid, alone or as a mixture.

72. Primary composition according to claim 65, wherein the lipophilic bioactive compound is a tomato extract, a soybean extract or a mixture thereof.

73. Primary composition according to claim 65, in the form of a powder, gel or liquid and which further comprises at least one of vitamin C or tocopherol.

74. Primary composition according to claim 65, which further comprises at least one of an emulsifier, a stabilizer or another additive.

75. Primary composition according to claim 65, wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition and the whey protein is present in an amount of about 5 to 90% by weight of the composition.

76. Primary composition according to claim 75, wherein the whey protein and lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.

78. Oral composition comprising the primary composition according to claim 65 in a foodstuff, in a food supplement or in a pharmaceutical preparation.

79. Oral composition according to claim 78, wherein the foodstuff is a yogurt, a liquid drink, a chocolate containing product, an ice cream, cereal, coffee or animal food.

80. Oral composition according to claim 78, wherein the food supplement further comprises at least one of a sweetener, a stabilizer, a flavoring or a colorant and is provided in the form of sugar-coated tablets, pills, gelatin capsules, a syrup, a gel or a cream.

81. Oral composition according to claim 78, wherein the content of the primary composition is between about 0.001 and 100% by weight of the oral composition.

82. Oral composition according to claim 81, wherein the content of the primary composition is between about 10 and 50% by weight of the oral composition.

86. The primary composition according to claim 72, wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition and the whey protein is present in an amount of about 5 to 90% by weight of the composition and wherein the whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.

87. Oral composition comprising the primary composition according to claim 86, in a foodstuff, in a food supplement or in a pharmaceutical preparation.

88. Oral composition according to claim 87, wherein the foodstuff is a yogurt, a liquid drink, a chocolate containing product, an ice cream, cereal, coffee or animal food, or the pharmaceutical preparation is provided in the form of sugar-coated tablets, pills, gelatin capsules, a syrup, a gel or a cream.

89. Oral composition according to claim 88, wherein the food supplement further comprises at least one of a sweetener, a stabilizer, a flavoring or a colorant.

90. Primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound, wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition and the whey protein is present in an amount of about 5 to 90% by weight of the composition and wherein the whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.

91. Oral composition comprising the primary composition according to claim 90, in a foodstuff, in a food supplement or in a pharmaceutical preparation.

92. Oral composition according to claim 91, wherein the foodstuff is a yogurt, a liquid drink, a chocolate containing product, an ice cream, cereal, coffee or animal food, or the pharmaceutical preparation is provided in the form of sugar-coated tablets, pills, gelatin capsules, a syrup, a gel or a cream.

93. Oral composition according to claim 92, wherein the food supplement further comprises at least one of a sweetener, a stabilizer, a flavoring or a colorant.

EVIDENCE APPENDIX

EXHIBIT A: Final Office Action dated August 3, 2006

EXHIBIT B: Advisory Action dated December 11, 2006

EXHIBIT C: U.S. Patent No. 5,643,623 to Schmitz et al. ("*Schmitz*"), cited by the Examiner in the Office Action dated August 3, 2006

EXHIBIT D: *Affidavit* of Karlheinz Bortlik under 37 C.F.R. §1.132

EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,660	01/25/2002	Karlheinz Bortlik	88265-6773	4348

29157 7590 08/03/2006

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EXAMINER	
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1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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BELL, BOYD & LLOYD
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Office Action Summary	Application No.	Applicant(s)	
	10/057,660	BORTLIK ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11-16-05; 6/22/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-76 and 78-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-76 and 78-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Petition to Revive filed on November 16, 2005 had been received and entered into the case. The Petition to Revive has been granted on June 22, 2006. The submitted amendment and response filed on November 16, 2005 has been received and entered into the case. Claims 65 – 76 and 78 – 93 are pending and have been considered on the merits. All arguments and appendices have been fully considered.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 65 – 76 and 78 – 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz et al. (US 5643623).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; the composition is a powder, gel or liquid; and the composition further comprises at least one of an emulsifier, stabilizer, or other additive. The LBC is 0.05 – 50% of the composition, the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, food supplement, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food; and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant additionally claims a composition with 0.001 – 100% or 10 – 50% of the claimed composition; as cosmetic

comprising the composition which further comprises a compound active to the skin; and a cosmetic comprising 10^-10 – 10% of the composition.

Schmitz teaches a human or animal food composition comprising 20 – 40% whey, 0.1 – 1% carotenoids, and 1.5 – 3.5% vitamin E and C (example 6). The antioxidant mixture may contain lycopene (abstract). Schmitz teaches the composition may be a solid, semi solid, liquid or gel (col.4 line 9-17). Specifically, Schmitz teaches a first component comprising 10 – 20% whey protein, 0.1 – 1% carotenoids, and 1.5 – 3.5% vitamin E and C (which are compounds active with respect to skin) (example 6), wherein the first component further comprises a lipid carrier, herbal extract or mineral supplement (or additives) (col.5 line 23-28) and corn syrup (a sweetener) (example 6). Schmitz further teaches that the first component is blended such that the ingredients are dispersed and mixed together (examples) and that the first component is present in food products at 5 – 60% (col.5 line 55-60).

Although Schmitz does not teach the source from which the LBC were obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Schmitz does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

In addition, although Schmitz does not teach the claimed function of the whey, the discovery of a previously unappreciated property of a prior art composition does not render the

old composition patentably new. Thus the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

Response to Arguments

Applicant argues that Schmitz does not teach a homogenous mixture of whey and LBC and that the reference does not teach the whey enhances bioavailability of the LBC.

However, these argument fail to persuade because as stated above, Schmitz clearly teaches a first component comprising whey and LBC that are mixed well together (or are homogenized) (examples). Moreover, Schmitz teaches the claimed ingredients in the claimed amounts, thus the composition of Schmitz must inherently perform the functions as disclose by applicant. Otherwise applicant's invention could not function as claimed. Further, it is noted that the instant claims do not require the mixture to be homogenized, thus the argument is not commensurate in scope with the claims.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

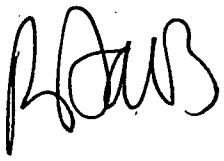
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



July 31, 2006

EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,660	01/25/2002	Karlheinz Bortlik	88265-6773	4348

29157 7590 12/11/2006

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/057,660	**Applicant(s)** BORTLIK ET AL.	
	Examiner Ruth A. Davis	**Art Unit** 1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *65-76,78-82 and 86-93*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Ruth A. Davis
Primary Examiner
Art Unit: 1651

Continuation of 11. does NOT place the application in condition for allowance because: applicant argues the reference does not teach a homogenous mixture of whey and LBC and provides a declaration stating the same. However, as indicated in the previous office action, the reference does in fact teach a composition wherein a combination of whey and LBC are combined together. It is reiterated that the claims do not require that the composition be homogenous, thus the argument is not commensurate in scope with the claims.

EXHIBIT C

US005643623A

United States Patent [19]

Schmitz et al.

[11] Patent Number: 5,643,623

[45] Date of Patent: Jul. 1, 1997

[54] **HEALTH FOOD PRODUCT AND ITS USES**

[75] Inventors: **Harold H. Schmitz**, Hackettstown; **Dana L. Michael**, Andover, both of N.J.; **James C. Neumann**, Stroudsburg, Pa.; **Michael Webster**, Blairstown, N.J.; **Elizabeth Zemenek**, Easton, Pa.; **Ralph Jerome**, Blairstown, N.J.

[73] Assignee: **Mars Incorporated**, McClean, Va.

[21] Appl. No.: **473,451**

[22] Filed: **Jun. 7, 1995**

[51] **Int. Cl.**[6] **A23L 1/302**

[52] **U.S. Cl.** **426/73**; 426/72; 426/74; 426/311; 426/541; 426/544; 426/648

[58] **Field of Search** 426/72, 73, 74, 426/311, 541, 544, 648

[56] **References Cited**

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(List continued on next page.)

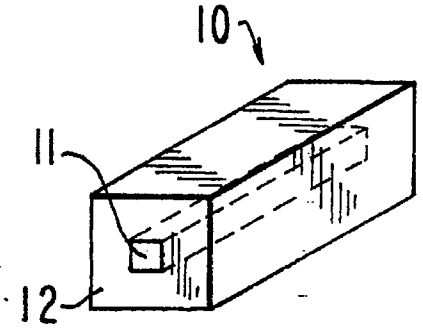
Primary Examiner—Helen Pratt

Attorney, Agent, or Firm—Curtis, Morris & Safford, P.C.

[57] **ABSTRACT**

A health food product containing a first component in the form of a discrete portion from a second component provides enhanced in vivo oxidative defense indices and prevents or attenuates exercise-induced in vivo oxidative stress as indicated by cellular and/or tissue modification. The first component includes an antioxidant mixture containing a blend of antioxidants selected from all-trans beta-carotene, a mixture of cis beta-carotenes, all-trans alpha-carotene, a mixture of cis alpha-carotenes, all-trans lycopene, a mixture of cis lycopenes, all-trans gamma-carotene, a mixture of cis gamma-carotenes, zeta-carotene, phytofluene, phytoene, vitamin C, vitamin E and curcumin. Internalization and integration of the above nutrients within a lipid containing core of the food product facilitates absorption of the fat-soluble components in the gastrointestinal tract following consumption, increases shelf-life and minimizes degradation of these labile compounds by minimizing exposure to heat, light and/or oxygen, and prevents disadvantageous yellow/orange coloration of the outer material of the food product.

25 Claims, 1 Drawing Sheet



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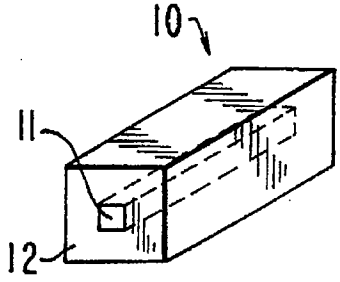

FIG. 1

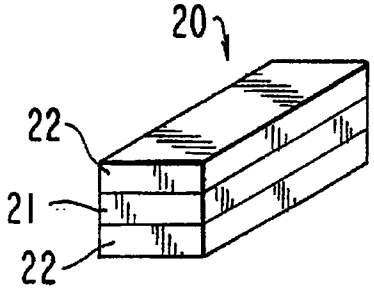

FIG. 2

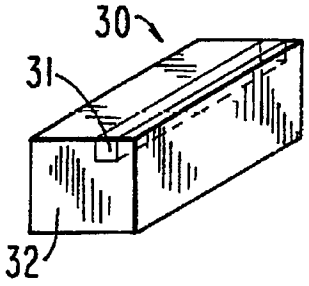

FIG. 3

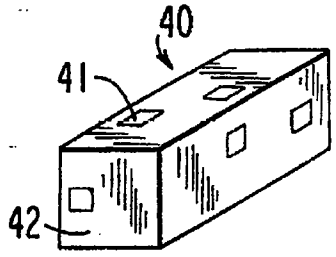

FIG. 4

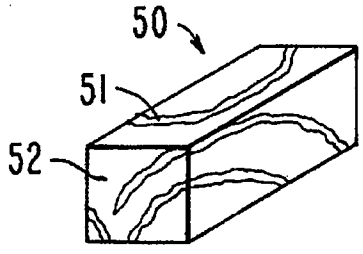

FIG. 5

HEALTH FOOD PRODUCT AND ITS USES

FIELD OF THE INVENTION

The present invention relates to the design and manufacture of a health food product which contains an edible first component containing an antioxidant, and an edible second component containing a carbohydrate and/or a fat and/or a protein. The first component is in the form of a discrete portion from the second component to protect the first component, to maximize absorption of the first component in the gastrointestinal tract and/or to provide a product having advantageous shelf-life and appearance.

The present invention also relates to a unique blend of antioxidant compounds which, upon consumption, increases in vivo oxidant defense indices and prevents or attenuates in vivo exercise-mediated oxidative stress as measured by cellular and/or tissue damage.

BACKGROUND OF THE INVENTION

Several publications are referenced in this application within parentheses. Full citation to these references is found at the end of the specification immediately preceding the claims. These references describe the state of the art to which this invention pertains, and are incorporated herein by reference.

The consumption of foods rich in antioxidant compounds is well-known to be inversely correlated with the incidence of many chronic disease states (Halliwell, 1994; Thomas, 1994; Ziegler, 1989). Intake of certain of these compounds, such as vitamins C, E and A, is in fact essential for human life. However, most of the natural compounds present in food possessing antioxidant potential are currently considered to be "non-nutritive". Given the preponderant accumulation of epidemiological data and increasing amount of mechanistic data which support an important role for antioxidants in the maintenance of long-term health, their status as "non-nutritive" food components may have to be reconsidered in the future.

The importance of oxidant defense systems in humans is demonstrated by the essential in vivo presence of both enzymatic as well as non-enzymatic antioxidant components (Thomas, 1994). Oxidative stress and resultant oxidative damage may occur as a result of oxidative insults such as air pollution or the "oxidative burst" characteristic of activated neutrophils mediated by the immune response. A constant source of oxidative stress results from formation of superoxide anion via "electron leakage" in the mitochondria during production of adenosine triphosphate (ATP). Although superoxide anion is not exceedingly reactive in and of itself, it can initiate a chain of events that eventually results in the formation of the highly reactive free radicals and other oxidants. If these reactive oxygen species are not controlled by enzymatic and/or non-enzymatic antioxidant systems, in vivo oxidation of critical cellular components such as membranes, DNA and proteins will result, eventually leading to tissue damage and dysfunction.

Intense exercise can contribute significantly to oxidative stress in a number of ways. Most individuals have at some time in their lives experienced soreness and fatigue after physical exertion. For individuals that desire intense, frequent exercising, the effects of oxidative stress can often inhibit the intensity and/or reduce the frequency of workout routines.

Intense exercise results in a number of physiological changes in the body. First, aerobic respiration is dramatically

increased, thereby increasing superoxide anion generation as much as 10-fold or more (Halliwell, 1994) in addition to increasing exposure to environmental oxidative insults such as air pollution. Second, muscle and joint inflammation often result from intense exercise, thus triggering tissue infiltration of neutrophils and subsequent release of reactive oxygen species during the "oxidative burst".

It would therefore be desirable to provide a shelf-stable, visually appealing and flavorful food product comprising carbohydrate and/or fat and/or protein, and other nutritive and non-nutritive compounds, that provides energy and alleviates the effects of oxidative stress and other damage resulting from intense exercise.

The following references, each of which are also incorporated herein by reference, further disclose the state of the art.

U.S. Pat. No. 4,451,488 to Cooke et al. discloses a shelf-stable, intermediate moisture, food bar having a soft and chewy texture, and low sugar content formed from a combination of at least two polyhydric alcohols in varying ratios, one of which comprises a sugar alcohol and the other either glycerol or propylene glycol (abstract). The food bar may additionally contain a mixture of dry ingredients selected from the group consisting of grains, fruits, nuts, chocolate chips and vegetables (column 3, lines 51–57).

U.S. Pat. No. 5,290,605 to Shapira discloses a nutritional soft drink for protecting against the danger of exposure to UV light comprising a mixture of carotenoids, optionally together with vitamin C and/or vitamin E and/or other physiologically acceptable antioxidants (abstract).

U.S. Pat. No. 5,234,702 to Katz discloses the incorporation of an antioxidant system of natural ingredients to minimize the oxidation of a powdered nutritional product (abstract). The antioxidant system is made up of ascorbyl palmitate, beta carotene and/or mixed tocopherols, and citrate (abstract and column 2, lines 56–59).

OBJECTS OF THE INVENTION

It is an object of the present invention to provide a food product comprising a unique blend of antioxidant components that enhance in vivo oxidant defense indices and reduce in vivo oxidant stress and damage resulting from intense exercise.

Further, it is an object of this invention to provide a food product that overcomes the food product development drawbacks of certain of the incorporated antioxidants; those drawbacks including disadvantageous yellow/orange color and chemical instability of the antioxidant blend to heat, light and oxygen (Schmitz et al., 1993; Encyclopedia of Food Science and Technology, 1991).

It is another object of the present invention to provide a food product with improved taste that maximizes absorption in the gastrointestinal tract of fat-soluble antioxidant components via localization within a lipid-based carrier formed within the food product.

SUMMARY OF THE INVENTION

The present invention relates to a food product which comprises a first component and a second component, wherein the first component is in the form of a discrete portion from the second component. The first component comprises an antioxidant, preferably an antioxidant blend, in addition to a carbohydrate and/or fat and/or protein, and other nutritive and non-nutritive compounds. The second component comprises a carbohydrate and/or fat and/or

protein, and other nutritive and non-nutritive compounds. The product delivers nutritive and non-nutritive compounds which improve the antioxidant defense system and reduce the occurrence of cellular damage secondary to exercise associated oxidative damage in humans.

Advantageously, the antioxidant blend comprises at least two antioxidants selected from the group consisting of curcumin, all-trans beta-carotene, cis beta-carotenes, all-trans alpha-carotene, cis alpha-carotenes, all-trans lycopene, cis lycopenes, all-trans gamma-carotene, cis gamma-carotenes, zeta-carotene, phytofluene, phytoene, vitamin C and vitamin E. The first component may also contain an antiinflammatory agent, for example a tumeric extract such as curcumin.

Advantageously, the antioxidants are concentrated in a core or discrete portion within the food product to provide protection from heat, light and oxygen and also to avoid disadvantageous coloration of the food product by the antioxidants. Preferably, the antioxidants are localized in a lipid-based carrier within the food product to promote absorption and digestion of the carotenoid blend and curcumin.

The present invention provides a method of increasing in vivo oxidant defense indices in an animal by administering a food product of the invention in an amount effective for increasing in vivo oxidant defense indices, and a method of attenuating in vivo exercise-mediated oxidative stress in an animal by administering a food product of the invention in an amount effective for attenuating in vivo exercise mediated oxidative stress.

Additional objects, advantages and features of the various aspects of the present invention will become apparent from the following description of its preferred embodiments, such description being given in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a perspective view of a food product in accordance with a preferred embodiment of the present invention containing a first component in the form of an internalized core within the second component;

FIG. **2** illustrates a perspective view of a food product in accordance with a preferred embodiment of the present invention containing a first component in the form of a sandwich layer between the second component;

FIG. **3** illustrates a perspective view of a food product in accordance with a preferred embodiment of the present invention containing a first component in the form of a strip on the second component;

FIG. **4** illustrates a perspective view of a food product in accordance with a preferred embodiment of the present invention containing a first component in the form of discrete chunks within the second component; and

FIG. **5** illustrates a perspective view of a food product in accordance with a preferred embodiment of the present invention containing a first component mixed with the second component to form random discrete striations within a marbleized product.

DETAILED DESCRIPTION OF THE INVENTION

Referring initially to FIG. **1**, a food product **10** is illustrated that includes an internalized core of first component **11** within second component **12**.

FIG. **2** illustrates a food product **20** that includes a layer of first component **21** sandwiched between second component **22**.

FIG. **3** illustrates a food product **30** that includes a strip of first component **31** on second component **32**.

FIG. **4** illustrates a food product **40** that includes discrete chunks of first component **41** within second component **42**.

FIG. **5** illustrates a food product **50** that includes a first component **51** mixed with a second component **52** to form random discrete striations within a marbleized product.

It should be appreciated that the food products illustrated in the figures can be in any convenient size and shape, including individual bite-sized pieces and other conventional confectionery food product sizes in square, rectangular, round, oval, spherical, elliptical, donut or other shapes. For the first component to form a discrete portion from the second component, the second component is advantageously solid or semi-solid and the first component is solid, semi-solid, a gel or a liquid.

It should be understood that the blend of antioxidant components described herein is chemically unstable toward excessive heat, light and oxygen. Upon exposure of this blend to excessive amounts of heat, light and/or oxygen, a loss of in vivo biological antioxidant activity will ensue. Thus, it is preferable to protect the antioxidant blend from heat, light and/or oxygen.

It should be further understood that absorption in the gastrointestinal tract of the fat-soluble components of said antioxidant blend is enhanced by the presence of adequate fat in the product and is further enhanced by direct incorporation into a lipid matrix within the food product. Advantageously, the absorption in the gastrointestinal tract of the fat-soluble components of the first component is enhanced by incorporating the first component into a lipid matrix separate from the second component while maintaining a product having a total fat content of preferably about 2% to about 40% by weight, more preferably about 2 to about 30 wt. %, even more preferably about 2 to about 20 wt. % and most preferably about 2 to about 15 wt. %. Incorporating the first component in a lipid portion that is separate from the second component provides for enhanced absorption without greatly increasing the overall fat content of the food product.

Finally, it should be appreciated that the distinctive yellow/orange pigmentation of certain of the biologically active compounds in the stated antioxidant blend is disadvantageous with respect to consumer visual appeal with the production of flavored products typically not associated with a yellow/orange color, including but not limited to banana, berry and chocolate flavors. Concentration of said pigments within a discrete portion, such as an internalized core, a layer, a strip, a chunk or marbleized striations, during manufacture of the product overcomes this problem. In this manner, the chemically unstable antioxidants are protected from heat, light and/or oxygen by being at least partially surrounded by the second component.

In addition, by maintaining the first component in the form of a discrete portion from the second component, the distinctive yellow/orange pigmentation of certain of the biologically active ingredients in the first component does not discolor the second component. This provides a food product with advantageous shelf-life and consumer visual appeal.

The first component comprises an antioxidant, preferably an antioxidant blend, and may further comprise a carbohydrate and/or fat and/or protein, and other nutritive and non-nutritive compounds. Advantageously, the antioxidant blend comprises at least two antioxidants selected from the group consisting of curcumin, all-trans beta-carotene, cis

beta-carotenes, all-trans alpha-carotene, cis alpha-carotenes, all-trans lycopene, cis lycopenes, all-trans gamma-carotene, cis gamma-carotenes, zeta-carotene, phytofluene, phytoene, vitamin C and vitamin E.

The first component may further comprise an antiinflammatory agent, advantageously a turmeric extract such as curcumin.

Preferably, the antioxidant is a nutritive antioxidant, and the antioxidant blend contains at least two nutritive antioxidants. The antioxidant blend may further contain a non-nutritive antioxidant.

Advantageously, the nutritive antioxidants are selected from the group consisting of provitamin A carotenes (including all-trans beta-carotene and cis beta-carotenes, all-trans alpha-carotene and cis alpha-carotenes, all-trans gamma-carotene and cis gamma-carotenes), vitamin C and vitamin E, and the non-nutritive antioxidants are selected from the group consisting of non-provitamin A carotenes (zeta-carotene, all-trans lycopene, cis lycopenes, phytofluene, phytoene, and curcumin) and an antiinflammatory agent.

The first component may further contain a lipid, for example long-chain saturated or unsaturated mono-, di- or tri-acylglycerols or medium-chain saturated or unsaturated mono-, di-, or tri-acylglycerols. Preferably, the first component comprises a lipid-based carrier to promote absorption of the lipid-soluble antioxidants in the gastrointestinal tract.

Preferably, the amount of antioxidants in the lipid-based carrier is about 10 to about 90 wt. %, more preferably about 15 to about 80 wt. %, even more preferably about 20 to about 70 wt. %, and most preferably about 30 to about 60 wt. % of the lipid-based carrier.

The first component may further contain an additional nutritive compound, such as a mineral supplement and B vitamins, or an additional non-nutritive compound, such as ginkgo biloba extract, ginseng extract, green tea extract, licorice extract or any other herbal compounds and/or plant-based extracts.

The second component comprises a carbohydrate and/or fat and/or protein, and advantageously other nutritive and non-nutritive compounds, such as a mineral, a vitamin, herbal compounds and other plant-based extracts.

In accordance with the present invention, the first component is at least partially surrounded by the second component to protect the first component from heat, light and oxygen, to promote absorption of the first component and to provide a product having advantageous shelf-life and appearance.

The first component may be in the form of an internalized core within the second component, in the form of a sandwich layer between the second component, in the form of a strip on the second component, in the form of a discrete chunk in the second component or mixed with the second component to form random discrete striations of a marbleized product.

Preferably, the first component is present in an amount of about 5 to about 60 wt. % of the food product, more preferably about 5 to about 50 wt. %, even more preferably about 5 to about 40 wt. % and most preferably about 5 to about 30 wt. %.

Preferably, the antioxidants are about 0.01 to about 4.0 wt. % of the food product, more preferably about 0.05 to about 3.0 wt. %, even more preferably about 0.10 to about 2.0 wt. % and most preferably about 0.20 to about 1.0 wt. %.

The present invention provides a method of increasing in vivo oxidant defense indices in a human or animal by administering a food product of the invention, and a method of attenuating in vivo exercise-mediated oxidative stress in a human or animal by administering a food product of the invention.

The present invention is further described and illustrated in the following examples. Further objects of this invention, together with additional features contributing thereto and advantages accruing therefrom, will be apparent from the following examples of the invention. It will be appreciated that variations and modifications to the products and methods can be made by the skilled person without departing from the spirit or scope of the invention as defined in the appended claims.

EXAMPLE 1

Ingredients for the first component are blended in such a way that the antioxidant compounds are dispersed in the lipid-based carrier and then mixed with the remaining ingredients. The remaining ingredients or a portion thereof may or may not be concentrated, though temperature/time parameters should ensure efficacy of all nutrients used. Any of a number of batch or continuous mixers may be used; the resultant mixture advantageously contains a homogeneous mixture of antioxidant compounds. Ingredients for the second component or a portion thereof may or may not be concentrated, and are blended in such a way that the resultant mixture is well mixed. Any number of batch or continuous mixers may be used. The first and second components are metered through a co-extruder in such a way that the first component is delivered as an internalized core within the second component. Various co-extruder nozzle designs, and adjustment of component feed rates may be used to deliver dual component systems of various size, shape and component percentage. The product can be further shaped after discharge from the co-extruder and is cooled, cut to desired length dimension if necessary, and packaged.

EXAMPLE 2

Ingredients for the first component are blended in such a way that the antioxidant compounds are dispersed in the lipid-based carrier and then mixed with the remaining ingredients. The remaining ingredients or a portion thereof may or may not be concentrated, though temperature/time parameters should ensure efficacy of all nutrients used. Any of a number of batch or continuous mixers may be used; the resultant mixture advantageously contains a homogeneous mixture of antioxidant compounds. Ingredients for the second component or a portion thereof may or may not be concentrated, and are blended in such a way that the resultant mixture is well mixed. Any number of batch or continuous mixers may be used. The second component is metered into a slab of desired height via depositing rolls or other appropriate process. The first component is metered into a slab of desired height via depositing rolls or other appropriate process and deposited on top of the second component. The second component is then metered into a slab of desired height via depositing rolls or other appropriate process and deposited on top of the first component, forming a product consisting of the first component sandwiched between the second components. The slab may be cooled, cut to desired width and length, and packaged.

EXAMPLE 3

Ingredients for the first component are blended in such a way that the antioxidant compounds are dispersed in the lipid-based carrier and then mixed with the remaining ingre-

dients. The remaining ingredients or a portion thereof may or may not be concentrated, though temperature/time parameters should ensure efficacy of all nutrients used. Any of a number of batch or continuous mixers may be used; the resultant mixture advantageously contains a homogeneous mixture of antioxidant compounds. Ingredients for the second component or a portion thereof may or may not be concentrated, and are blended in such a way that the resultant mixture is well mixed. Any number of batch or continuous mixers may be used. The first and second components are metered through a co-extruder in such a way that the first component is delivered as a strip on the second component. Various co-extruder nozzle designs, and adjustment of component feed rates are used to deliver dual component systems of various size, shape and component percentage. The product is cooled, cut to desired length dimension if necessary, and packaged. An alternative method would incorporate specially designed depositing rolls to deliver the second component in a slab with properly sized channel(s). An extruder is used to deposit the first component into the channels of the second component. The product is cooled, cut to desired length dimension if necessary, and packaged.

EXAMPLE 4

Ingredients for the first component are blended in such a way that the antioxidant compounds are dispersed in the lipid-based carrier and then mixed with the remaining ingredients. The remaining ingredients or a portion thereof may or may not be concentrated, though temperature/time parameters should ensure efficacy of all nutrients used. Any of a number of batch or continuous mixers may be used; the resultant mixture advantageously contains a homogeneous mixture of antioxidant compounds. Ingredients for the second component or a portion thereof may or may not be concentrated, and are blended in such a way that the resultant mixture is well mixed. Any number of batch or continuous mixers may be used. The first component is extruded and cut, or slabbed and cut to the desired particulate size and shape, and should be further processed to keep the particulates free-flowing. The first component is metered into the second component at a rate which delivers the desired weight ratios of the two. The mixing of the first and second components is gentle enough to insure that the first component remains a discreet particulate. The resultant mixture is metered into a slab of desired height via depositing rolls or other appropriate process. The slab may be cooled, cut to desired width and length, and packaged.

EXAMPLE 5

Ingredients for the first component are blended in such a way that the antioxidant compounds are dispersed in the lipid-based carrier and then mixed with the remaining ingredients. The remaining ingredients or a portion thereof may or may not be concentrated, though temperature/time parameters should ensure efficacy of all nutrients used. Any of a number of batch or continuous mixers may be used; the resultant mixture advantageously contains a homogeneous mixture of antioxidant compounds. Ingredients for the second component or a portion thereof may or may not be concentrated, and are blended in such a way that the resultant mixture is well mixed. Any number of batch or continuous mixers may be used. The first and second components are metered into another mixer which serves to "fold" the components together, creating random and discrete striations within the marbleized product matrix. The resultant mixture is metered into a slab of desired height via depositing rolls or other appropriate process. The slab may be cooled, cut to desired width and length, and packaged.

EXAMPLE 6

A health food product having the following formulation was prepared:

	Range %'s	
Ingredients	First Component	Second Component
Corn Syrup	30–40%	20–30%
Whey Protein Concentrate	10–20%	10–20%
Dehydrated Apples	—	20–30%
Dehydrated Cranberries	—	5–10%
Crystalline Fructose	10–20%	—
Fig Paste	5–10%	—
Dextrose	—	5–10%
Maltodextrin	10–20%	5–10%
Liquid Fructose	5–10%	5–10%
Glycerin	1–5%	1–5%
Vegetable Oil	1–5%	1–5%
Turmeric Extract	0.1–1.0%	—
Carotenoid Blend	0.1–1.0%	—
Vit. E & C Premix	1.5–3.5%	—
Calcium Carbonate	—	2–4%
Mineral Premix	—	2–4%
Flavor	—	0.25–1.5%
Color	—	0.10–1.0%
Malic Acid	—	1–2%

EXAMPLE 7

An experimental design incorporating 20 dedicated (20–25 miles/week) runners was developed to test clinically the efficacy of the unique blend of antioxidants comprising curcumin, all-trans beta-carotene, cis beta-carotenes, all-trans alpha-carotene, cis alpha-carotenes, all-trans lycopene, cis lycopenes, all-trans gamma-carotene, cis gamma-carotenes, zeta-carotene, phytofluene, phytoene, vitamin C and vitamin E. Each subject was screened for diet, drug use, supplement use and age. During the first 8 weeks, 10 subjects consumed a placebo bar while 10 subjects consumed the actual food bar described in Example 6 made by the procedure described in Example 1. Following an 8 week washout period, the 2 groups of subjects crossed over with respect to consumption of the placebo or actual food bar. Serum, urine and expired breath samples were collected at appropriate times. The following parameters were tested:

1. measurement of oxidant defense indices
   a. non-enzymatic oxidant defense indices present in serum (carotenoids, vitamin E, vitamin C, curcumin, glutathione)
   b. enzymatic oxidant defense indices present in serum (intracellular and extracellular superoxide dismutase, ceruloplasmin)
2. measurement of oxidative stress
   a. low density lipoprotein susceptibility to peroxidation
   b. carbonyls in expired breath
   c. protein carbonyls in serum
   d. serum and urinary lipoperoxides
   e. formation of DNA cross-link products
   f. non-enzymatic prostanoids
3. measurement of oxidative stress via inflammatory related processes
   a. thromboxane A2 production/platelet aggregation

b. serum and urinary prostacyclin

c. eicosinoid synthesis

d. platelet lipoxygenase

The data collected during the clinical experiment described above confirm that the food product containing the described blend of antioxidant compounds and nutrients increases in vivo oxidative defense indices and decreases in vivo oxidative stress.

As illustrated by the foregoing description and examples, the present invention has great application for the formulation of a wide variety of edible products. The present invention provides for edible products which, upon consumption, increase in vivo oxidant defense indices and prevent or attenuate in vivo exercise-mediated oxidative stress as measured by cellular and/or tissue damage, without detrimentally affecting the taste, texture and appearance of the product.

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We claim:

1. An edible food product, which comprises

(a) an edible first component containing an antioxidant having in vivo biological antioxidant activity and

(b) an edible second component containing an ingredient selected from the group consisting of a carbohydrate, a fat and a protein, and combinations thereof, said second component positioned for protecting the in vivo biological antioxidant activity of the antioxidant in the first component,

wherein the first component is in the form of a discrete portion from the second component, wherein the antioxidant is an antioxidant blend containing at least two nutritive antioxidants selected from the group consisting of all-trans beta-carotene, cis beta-carotenes, all-trans alpha-carotene, cis alpha-carotenes, all-trans gamma-carotene, cis gamma-carotenes, vitamin C and vitamin E, and wherein the antioxidant blend further contains a non-nutritive antioxidant selected from the group consisting of zeta-carotene, all-trans lycopene, cis lycopenes, phytofluene, phytoene and an anti-inflammatory agent.

2. The food product of claim 1, wherein the antiinflammatory agent is a turmeric extract.

3. The food product of claim 2, wherein the turmeric extract is curcumin.

4. The food product of claim 1, wherein the first component further contains a lipid.

5. The food product of claim 4, wherein the lipid is long- or medium-chain saturated or unsaturated, mono-, di-, or tri-acylglycerols.

6. The food product of claim 1, wherein the first component further contains an ingredient selected from the group consisting of a carbohydrate, a fat and a protein, and combinations thereof.

7. The food product of claim 1, wherein the first component further contains an additional nutritive or non-nutritive compound, or mixtures thereof.

8. The food product of claim 7, wherein the additional nutritive compound is selected from the group consisting of a mineral supplement and B vitamins.

9. The food product of claim 7, wherein the additional non-nutritive compound is selected from the group consisting of herbal compounds and other plant-based extracts.

10. The food product of claim 1, wherein the second component further contains a compound selected from the group consisting of a mineral, a vitamin, a herbal compound and a plant-based extract.

11. The food product of claim 1, wherein the first component is at least partially surrounded by the second component to protect the first component from heat, light and oxygen.

12. The food product of claim 11, wherein the first component is in the form of an internalized core.

13. The food product of claim 11, wherein the first component is in the form of a layer.

14. The food product of claim 11, wherein the first component is in the form of a strip.

15. The food product of claim 11, wherein the first component is in the form of a chunk.

16. The food product of claim 11, wherein the first component is mixed with the second component to form random discrete striations of a marbleized product.

17. A method of increasing in vivo oxidant defense indices in an animal, which comprises administering to the animal a food product as defined in claim 1 in an amount effective for increasing in vivo oxidant defense indices in the animal.

18. A method of attenuating in vivo exercise-mediated oxidative stress in an animal, which comprises administering to the animal a food product as defined in claim 1 in an amount effective for attenuating in vivo exercise-mediated oxidative stress in the animal.

19. An edible food product, which comprises

(a) an edible first component in a lipid/carbohydrate system containing at least one nutritive antioxidant selected from the group consisting of all-trans beta-carotene, cis beta-carotenes, all-trans alpha-carotene, cis alpha-carotenes, all-trans gamma-carotene, cis gamma-carotenes, vitamin C and vitamin E, and at least one non-nutritive antioxidant selected from a group consisting of zeta-carotene, all-trans lycopene, cis lycopenes, phytofluene, phytoene and an anti-inflammatory agent,

(b) an edible second component containing at least one ingredient selected from the group consisting of a carbohydrate, a mineral, a fat and a protein, and combinations thereof,

wherein the first component is in the form of an internalized core portion discrete from the second component and at least partially surrounded by the second component to protect the first component from heat, light and oxygen.

20. The food product of claim 19, wherein the first component contains at least two nutritive antioxidants.

21. The food product of claim 19, wherein the antiinflammatory agent is a turmeric extract.

22. The food product of claim 21, wherein the turmeric extract is curcumin.

23. The food product of claim 19, wherein the lipid is long- or medium-chain saturated or unsaturated, mono-, di-, or tri-acylglycerols.

24. The food product of claim 19, wherein the first component further contains an additional non-nutritive compound selected from the group consisting of herbal compounds and other plant-based extracts.

25. The food product of claim 19, wherein the second component further contains a compound selected from the group consisting of a vitamin, a herbal compound and a plant-based extract.

* * * * *

EXHIBIT D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): K. Bortlik et al.
Appl. No.: 10/057,660
Conf. No.: 4348
Filed: January 25, 2002
Title: PRIMARY COMPOSITION COMPRISING A LIPOPHILIC BIOACTIVE COMPOUND
Art Unit: 1651
Examiner: R.A. David
Docket No.: 112701-593

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:
- Diploma in Biology and Ph.D. in Plant Physiology (University of Zurich, Switzerland)
- Since 1995 at Nestlé Research Center with various projects on colour stabilisation in food, extraction of plant constituents. Current projects: Functionalisation of bioactives for improved delivery.

2. I am the named inventor of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated August 3, 2006 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the reference cited therein as well as the pending claims. I believe that the anticipation rejection of Claims 65-76 and 78-93 under 35 U.S.C. §102(b) based on U.S. Patent No. 5,643,623 to Schmitz et al. ("*Schmitz*") is based on a misunderstanding of the reference and the pending claims. The basis for my opinion is set forth below.

4. The present invention is directed, in part, to a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound ("LBC") and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. For example, a process for the preparation of the oral primary composition comprises associating the whey protein with the lipophilic bioactive compound under conditions sufficient to form the composition a mixture. The composition may be formed by dissolving the whey protein in water to form a first solution, dissolving the lipophilic bioactive compound in a solvent to form a second solution, combining the two solutions, and evaporating the solvent to form the composition as a dispersion. Alternatively, the composition may be formed by mixing the lipophilic bioactive compound with a solvent to form a first mixture, mixing the first mixture with the whey protein in the form of a powder to form a second mixture and evaporating the solvent from the second mixture to produce the composition as a dry powder.

5. The present invention relates to increasing the bioavailability of a lipophilic bioactive compound by the novel feature of associating the lipophilic bioactive compound with a whey protein to form a mixture. By mixing an LBC with a whey protein, the present invention makes available to a subject an LBC-containing composition with better bioavailability compared to consuming an LBC alone. As summarized in Example 1 of the present specification, administration of the claimed composition -- formed by mixing a lipophilic bioactive compound, such as lycopene, with a whey protein in a mixture form -- has shown that the composition's LBC bioavailability is comparable to that of tomato puree or paste, which is known to have the best bioavailability of lycopene.

6. As one having ordinary skill, I believe that *Schmitz* does not disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. *Schmitz* teaches a health food product containing a first component in the form of a discrete portion within a second component. The first component includes antioxidants selected from carotenoids, vitamins C and E, and curcumin. *Schmitz* teaches internalization and integration of the above

nutrients within a lipid-containing core of the food product. Because *Schmitz* teaches putting antioxidants in a lipid-based core, the antioxidants in *Schmitz's* composition are in an internalization and heterogeneous form. In contrast, the composition of the present invention is a homogenous mixture of the LBC and whey protein.

7. As one having ordinary skill, I believe that *Schmitz's* product does not achieve enhancing bioavailability of the LBC with whey protein in accordance with the present invention. *Schmitz's* teaches protecting compounds from oxidation via internalization or containing within a lipid core. *Schmitz* specifies that the antioxidants are localized in a lipid-based carrier within the food product. *Schmitz* does not teach increasing the bioavailability of the LBC by dispersion of the LBC in a matrix of whey proteins in accordance with the present invention. In contrast to the discrete internalization form in a lipid-based carrier taught by *Schmitz*, the LBC is distributed uniformly throughout the whey protein in the present invention, thereby providing the unexpected and important benefit of increased bioavailability of the LBC. The compound of *Schmitz* would not result in increased bioavailability of the LBC because it is at least partially surrounded in the lipid-based core. As a result, I believe that *Schmitz's* product does not inherently achieve the same function as the claimed invention.

8. For all the foregoing reasons, as one having ordinary skill in the art, it is my opinion that *Schmitz* fails to teach or suggest the claimed primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. I believe that *Schmitz* teaches that the antioxidants are preferably localized in a lipid-based carrier within the food product, which does not disclose, teach or suggest that the lipid core may be eliminated and replaced with whey protein as a mixture. I also believe that the function and benefit of the present mixture composition could not have been inherent in the at least partially surrounded *Schmitz* composition because of their significant differences in form and functional properties.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 13/11/06

Print Name Karlheinz Bortlik

RELATED PROCEEDINGS APPENDIX

None.